the ZOOLOGICAL SOCIETY of PHILADELPHIA

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ANIMAL HEALTH DEPARTMENT | **FAX TRANSMITTAL**

TO: Dockets Management Branch (HFA-305)
Food and Drug Administration
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MESSAGE: Response to request for comments on development of options to encourage drug approvals for minor species and for minor uses
DOCKET # 97N-0217

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the Zoological Society of Philadelphia

8.September.97

Dockets Management Branch (HFA-305)
Food and Drug Administration
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Regarding: 21CFR Chapter 1
Docket No. 97N-0217 - Request for comments on development of options to encourage animal drug approvals for minor species and for minor uses

To Whom It May Concern:

As Chair of the Legislation and Animal Welfare Committee of the American Association of Zoo Veterinarians (AAZV), I wish respond to above request for comments regarding animal drug approvals for minor species and for minor uses (**Docket No. 97N-0217**). On behalf of the membership of the AAZV, I thank you for providing us with this opportunity to contribute to this discussion.

Zoologic veterinarians are responsible for veterinary management of a myriad of animals and animal species. As noted in the 23June97 Federal Register, there are very few animal drugs specifically approved for use in the vast majority of these zoologic species. As a result, zoologic veterinary practitioners must utilize extra-label drug use provisions of AMDUCA extensively.

Zoologic specimens from institutions accredited by the American Zoo and Aquarium Association (AZA) do not impact food safety issues in that they are not consumed as human food. It is recognized and acknowledged that some traditionally zoologic species are finding markets as specialty food items. It would be short-sighted to imagine that drugs approved for use in zoologic species for which there are specialty markets would not or might not be utilized in managing animals destined for human consumption. Nonetheless, I will limit my remarks to those aspects of minor species/minor use that most affect the practice of zoologic medicine in zoologic institutions.

A. Scope - It is respectfully requested that the criteria found in **section 514.1(d)(1)** for determination of a minor species or a minor use be broadened to include uses other than for disease management. Sedation, anesthesia, behavior modification, and contraception or reproductive enhancement are examples of broad-based conservation and other non-disease applications that are of paramount importance in the many minor species that comprise zoologic veterinary practice.

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B. Creating Additional Statutory Authority -

1. *Should there be different standards for target animal safety and effectiveness of new animal drugs intended for use in minor species and for minor use.*

AZA institutions house limited numbers of specimens of many related zoologic species. It is impractical, from both conservation and financial standpoints, to suggest that determination of safety and efficacy of given drugs in each of these species be requiredprior to approval for minor species/use.

While it is ackowledged that there are or may be distinct species differences in response to a given drug, it is suggested that a broader application of data to related species (genera or families) be permitted.

2. *Should the standards be the same for all minor species and uses?*

It is respectfully submitted that it is not practical to subject all minor species/uses to the same standard(s). However, it might be both practical and appropriate to create **standards for use categories** (for example, for sedation of non-food hooved animals).

3. *Should products be labeled to reflect the use of different standards?*

Yes.

4. *If the Act were amended...how would appropriate doses be determined?*

The easiest response to make here is that the dose that works is the appropriate dose. This is obviously a simplistic response, as effect may be affected by age, gender, metabolic state, nutritional condition, reproductive stage, and a variety of evironmental and other considerations.

Most AZA institutions participate in a program known as ISIS (International Species Information System), a computerized database with programs that facilitate the collection and documentation of species-specific information. The ISIS MedARKS program (for medical records) includes both Anesthesia and Prescription modules. Information gleaned from these modules may help to elucidate effective doses of numerous commonly used (extra-label) drugs under a wide range of conditions and for a wide variety of animals. Perhaps such existing databases --that contain both subjective or anecdotal and objective information-- might be used to supplement limited documented drug research for minor species/uses.

5. *Would sponsors and users accept conditional approval with post-market surveillance?*

Yes.

6. *Should a drug approved under such a mechanism bear labeling that reflects its status?*

Yes.

7. *Should the act be amended to allow FDA to accept foreign reviews or approvals for minor species/use?*

Yes, provided that the standard of testing, use, documentation and

re-evaluation can be verified. How this verification may proceed is open to question; the following response may be appropriate to this, as well.

8. *Should the current statutory standard...or any alternative standard be implemented through a primary review process externalto the agency? How might the process be administered and who should pay for the external reviews?*
The process of review *might* proceed more expeditiously were the primary review carried out external to the agency. There are many professional veterinary associations (including - to name but a few - the American Association of Zoo Veterinarians, the Association of Avian Veterinarians, the International Association of Aquatic Animal Medicine, and the Wildlife Disease Association) that cater to practitioners who provide care to specific species or groups of species. Members of these associations already generate and share a great deal of pharmacologic data. Thus, there are individuals with the knowledge to perform the reviews. In addition, there need not be only a single review group or board, as long as a clearinghouse for information is available, perhaps through the agency.

9. *Could determinations of animal safety and effectiveness by expert panels and compendia be used to support drug approvals for minor species/uses?*
Yes. Again, such organizations as the American Association of Zoo Veterinarians, the Wildlife Disease Association, the Association of Reptilian and Amphibian Veterinarians, etc, as well as veterinary academicians could provide the expertise required to man these review panels.
What information should be used?
Compilations of field and well-documented anecdotal data (for example, from the ISIS or other databases) with scientific controlled studies could be utilized to assess efficacy and safety and determine effective/appropriate drug dosages.
Should the determinations of the panels be issued as monographs, etc?
Yes.
Who should draft the monographs or standards?
Experts in the appropriate field(s). See responses 8 and 9, above.

I must add as a caveat to the preceeding that there must be some mechanism by which members of an expert panel can be held harmless for unanticipated adverse effects of or idiosyncratic reactions to drugs approved in good faith. Otherwise, no one is his/her right mind would sit on one of these proposed panels.

D. Creating Incentives
1. *Should a program similar to the National Research Support Program #7...be developed for wildlife and zoo animals and/or for production purposes? Should the program be expanded to cover such uses?*
I am insufficiently versed in NRSP#7 to comment as to whether it would be more appropriate to expand its scope or to create a

separate but similar program for wildlife and zoo animals. However, a mechanism for providing support to minor species/use research is both essential and urgently needed.

2. *Could/should philanthropic, public-interest, other not-for-profit organizations be encouraged to fund research for the development of new animal drugs intended for minor species/use?*
Yes. However, experience suggests that unless the scope of a given project to be funded is quite plain at the outset - particularly as regards FDA or other requirements (testing procedures, replicates, etc) for minor drug/species approval -these type organizations will be most reluctant to invest their highly sought-after dollars in minor species/drug research.

3. *Are there mechanisms other than the NADA process and extralabel uses of animal and human drugs under the AMDUCA that could enhance drug availability for minor species/uses?*
Except as regards products produced outside the United States, extralabel usage under AMDUCA has been most beneficial.

Thank you so much for your consideration of these issues.
Sincerely,

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